



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0848]

Compliance Policy Guide Regarding Canned Ackee, Frozen Ackee, and Other Ackee Products--
Hypoglycin A Toxin; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the Compliance Policy Guide (CPG) Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products--Hypoglycin A Toxin. The CPG provides guidance for FDA staff on our enforcement criteria for canned ackee, frozen ackee, and other ackee products that contain hypoglycin A.

DATES: Submit either electronic or written comments on the CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-827-3670. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the CPG to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Yingqing Ma, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1700.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products--Hypoglycin A Toxin. The CPG is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The CPG represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the Federal Register of November 8, 2012 (77 FR 67013), we announced the availability of draft CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products --Hypoglycin A Toxin and gave interested parties an opportunity to submit comments by January 7, 2013, for us to consider before beginning work on the final version of the CPG. We received one comment that did not pertain to the draft CPG. We are issuing the final version of the CPG with editorial changes, but with no substantive changes.

The CPG announced in this notice finalizes the draft CPG dated November 2012.

II. Comments

Interested persons may submit either written comments regarding the CPG to the Division of Dockets Management (see ADDRESSES) or electronic comments regarding the CPG to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received

comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the CPG from FDA's Office of Regulatory Affairs CPG history page at

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm>

or from <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: April 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.